

Swiss public not for GE crops

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In a referendum, the Swiss public voted in favor of a national ban on growing genetically engineered (GE) crops for five years.

"Switzerland, the homeland of genetic engineering giant Syngenta, is clearly unwilling to risk health, food security or the environment by allowing crops to be genetically engineered. Today's GE crop ban will help defend against these risks but will not provide full protection," said Yves Zenger from Greenpeace Switzerland.

GE field trials will still be allowed under the new moratorium and products deriving from animals fed on GE crops can still be imported into the country. Pending applications for GE food and animal feed could also still be approved.

A new opinion poll released by Greenpeace shows that the majority of Swiss people want the moratorium to go further because they are not only against GE crops but also reject GE food and believe field trials are risky. A vast majority also wants mandatory labelling of any products derived from animals fed on GE crops.

"Greenpeace hopes Switzerland's rejection of GE crops inspires others around the world to stand up and say 'no' to genetic engineering. We also encourage the Swiss public to continue to voice its opposition to this highly risky technology. Every route of contamination must be closed before people can rest assured their plants and the food on their plates is not contaminated," said Geert Ritsema, Greenpeace International GE campaigner.

BII launches e-learning courses

Delhi-based Bioinformatics Institute of India (BII) has made available its various certifications online with the launch of "BII Online" an enhanced system of providing e-Learning via internet. To start with all the specialized courses in biomedical sciences have been incorporated and can be joined by aspiring students. The site comprises of additional features like live virtual classroom demo, custom solutions, learning methodologies, online store, etc.

Puneet Mehrotra, director, Bioinformatics Institute of India, said, "The goal of BII Online is to be a leader in developing and providing quality online programs using the latest distance learning technology. The Institute's online programs were developed to serve a constituency of students with life constraints preventing them from attending campus-based classes. These eLearning programs provide maximum flexibility without compromising learning outcomes or academic rigor."

Ban GM food crops: Greenpeace

Greenpeace has unveiled a "biohazard hotspots map" revealing the scale of field trials of genetically engineered (GE) food crops in India. Its activists met the union health minister, Dr Anbumani Ramadoss and pointed out the urgency with which the ministry of health must step in and focus on health impacts of GE food.

In this context, Greenpeace also met with officials at the Indian Council of Medical Research (ICMR) who shared with the activists the minutes of a meeting of the Expert Committee on Genetically Modified (GM) Food held on September 6, 2005 at ICMR headquarters, New Delhi.

The ICMR officials have further asked Greenpeace to provide inputs into the document. Although Greenpeace has welcomed the process of open consultations and is studying the document, it reiterated that open-air field trials of GMOs are going on and the current system is woefully inadequate to combat runaway contamination. Greenpeace cautioned that inspite of ICMR's best intent and recommendations, the regulatory machinery will lag behind in its ability to prevent GMO proliferation from existing open-air field trials of GM foods which could lead to food contamination.

It has demanded a ban on all field trials of GE food crops in the country; all data on ongoing field trials of GE food be made public; and the new biotech policy be reoriented to focus on biosafety concerns and risks to health caused by GE foods.

HCL jointly launches Panax finder

HCL Technologies, a leading global IT solutions provider in Information Technology and Saila Systems Inc., Japan have launched Panax Finder, a statistical analysis software package which can be used by pharmaceutical companies in the drug discovery process. Saila Systems is one of the leading IT solution companies in Japan providing a range of services from software requirement analysis to systems supports jointly. This software will help pharmaceutical companies to identify the properties of the drug and predict its efficiency even before its synthesis, thereby gaining tremendously on time.

Pradeep Nair, vice president and head of Life Sciences Practice, HCL, New Jersey, USA said, "With the increasing maturity and complexity in IT environments today, we felt the need to provide our customers a tool that would reduce time inefficiency in drug discovery caused due to multitude of possibilities in which compounds can combine and synthesize and help them in saving cost."

ACCUFORD Tri-Tstat reagent kit launched

ReaMetrix and Millipore India have announced the release of the ACCUFORD Tri Tstat reagent kit. The kit enables a critical test for the management of AIDS patients to be available at a reasonable cost. ReaMetrix's goal for the test is reduce the cost to measure of the strength of a HIV patient's immune system and allow them to be tested more frequently.

Through this diagnostic, doctors will be able to assess when to begin drug therapy for AIDS and the effectiveness of that drug therapy. The reagent kit provides the consumables for the enumeration of a patient's T-cells on a flow cytometer. The key component of this test are fluorescently-labeled monoclonal antibodies.

While the raw materials for the test are imported from established suppliers in developed nations, the process for creating a clinically seful kit is carried out entirely in India. The reagent kit will be developed and manufactured in India by ReaMetrix and marketed by Millipore India.

Sun Pharma acquires Able Labs

Sun Pharma, a speciality pharma company, has successfully completed the purchase of dosage form manufacturing operations of Able Labs in the US for \$23.15 million by its wholly owned subsidiary company, Sun Pharmaceutical, Michigan. The US Bankruptcy Court of the District of New Jersey, Trenton, had accepted the Sun Pharma bid as the highest, earlier this year.

These assets include ownership and lease rights to manufacturing operations at two sites in New Jersey, with total 275,000 sq.ft. floor area, including special suites for the manufacture of controlled substances. The purchase also includes intellectual property for the products being marketed by Able until it was required by the USFDA to withdraw these earlier this year, as also products under approval.

Sun Pharma will evaluate and revalidate these dossiers and resubmit selected products with the USFDA. These products, on launching, are expected to make a significant addition to the company's US generic business. This is Sun Pharma's fourth acquisition in the US, the other three being the acquisition of Caraco in 1997, the acquisition of two brands from Women's First Healthcare in 2004, and the purchase of a dosage form plant at Bryan, Ohio earlier in September this year. Caraco's business was built from sales of \$ 0.8 million in 1997 to over \$ 60 million in 2004. Sun Pharma continues to evaluate further acquisition opportunities in the US.

Glenmark signs pact with InvaGen

Mumbai-based Glenmark Pharmaceuticals Ltd and US-based InvaGen Pharmaceuticals, entered into a collaboration agreement for the joint development, filing and marketing of seven generic pharmaceutical products for the US market. The product list includes a mixture of off-patent and patent-protected molecules with cumulative annual sales in the US of about \$4.1 billion.

As per the agreement, InvaGen will develop and license to Glenmark, seven generic products. InvaGen will also undertake filing the ANDAs while Glenmark will be responsible for obtaining regulatory approval in the US market. Upon approval, Glenmark's US subsidiary, Glenmark Pharmaceuticals, will exclusively market the products while InvaGen will be responsible for their manufacture and supply. All development and regulatory costs and profits on sale in the US will be shared equally between Glenmark and InvaGen. Of the list, one ANDA has already been filed till date and three more are expected to be filed by March 2006.

SPI Pharma launches India operations

SPI Pharma, a fully owned subsidiary of Associated British Foods company and a worldwide leader in custom formulation solutions for pharmaceutical manufacturers, has commissioned a full-fledged drug development and testing center in Bangalore. The development center is housed in a 16,000 sqft. building with room for expansion located at Veerasandra Industrial Estate. The facility was inaugurated by Dr Venkateswarlu, deputy drugs controller of India, recently. SPI operations in India are scheduled to begin by January 1, 2006. The work will involve drug development and discovery.

John Burrow, CEO, SPI Holdings said, "With India fast becoming a scientific powerhouse in the global pharma market, this new facility is significant to our operations in India. SPI Pharma will be in a position to speed up customized projects using several of its proprietary excipients and delivery platforms. SPI's strategy in India is to develop and test finished drugs using its proprietary drug delivery technologies as well as those acquired through strategic partners."

Rana Kayal, president SPI Pharma said, "SPI's major strengths are functional modification of pharmaceutical materials and enabling drug delivery technologies. SPI Pharma has made an investment of over Rs 4 crore in this new facility and plans to increase it based on the needs of the clients. Our products will be made available to pharma companies around the globe. We are currently working with companies like Cipla, Novartis, Pfizer and Dr Reddy's in India. We are also in discussions with major API producers like Matrix and Biocon," he added.

NPIL signs pact with Pfizer International

Nicholas Piramal India Limited (NPIL), has signed a long-term contract manufacturing related R&D services agreement with Pfizer International LLC. The agreement is for a period of seven years, and is renewable thereafter.

Strides gets RBI go-ahead for FII holding

Strides Arcolab Ltd, a Bangalore-based pharma company has received permission from the Reserve Bank of India permitting the Foreign Institutional Investors (FIIs) to hold up to 49 percent of paid-up equity capital of the company. FII holding in the

company's scrip had reached the previously approved limit of 24 percent.

Monsanto to import parental lines of transgenic corn

Monsanto India Ltd has received approval from Genetic Engineering Approval Committee (GEAC) to import parental lines of herbicides tolerant corn to carry out research in the country. It will import transgenic corn seed (250 gm), 50 gm each of four inbred lines and one single cross from Monsanto Republic of South Africa subject to certain conditions.

The conditions are as follows: the import of transgenic corn seeds shall be exclusively for the purpose of research and shall be carried out in accordance with conditions and safe guards stipulated by the Review Committee on Genetic Manipulation (RCGM) and National Bureau on Plant Genetics and Research (NBPGR), the authorized agencies for granting permission to import transgenic materials for the purpose of research; the research proposal shall have the prior approval of RCGM before initiating the research activity; the clearance will not be treated as blanket approval for product development. The product development if any shall be done in accordance with the procedure prescribed by RCGM and GEAC.

Opto Circuits acquires German firm

Opto Circuits (India) Ltd (OCIL), a manufacturer of non-invasive healthcare equipment based in Bangalore, has completed the acquisition of EuroCOR GmbH, a German company that designs and manufactures various kinds of stents. The acquisition has been valued at Euro 11 million (Rs 59.91 crore).

Announcing the acquisition, Vinod Ramnani, chairman and managing director, OCIL said, "This acquisition of EuroCOR gives us a strong foothold in the global arena for stents. The total global market for stents was valued at \$6 billion in 2004 and is expected to rise at \$10 billion by 2008. Whilst we are barely scratching the surface now, we expect that the strong R&D base of EuroCOR will lead us in the direction of greater market share and also better margin business. This acquisition is another milestone in the history of the growth of Opto Circuits, and will help improve shareholder value."

Bharat Serums gets US patent

Bharat Serums and Vaccines Limited (BSVL) received a US patent for its novel formulation Amphotericin B Emulsion. All the excipients used for this formulation are US FDA approved for injectable formulations.

According to an official press release, comparative tests on animals have shown this formulation to be many times safer than any of the existing Amphotericin formulations. Amphotericin B has been considered to be the gold standard in the treatment of fungal infections. However, Amphotericin is highly nephrotoxic, which limits the usage of the drug.

Despite introduction of newer anti-fungal formulations into the market, there continues to be an interest in Amphotericin formulations "primarily due to the fact that over a period of time, the fungi build resistance to the anti-fungal agents.

BSVL has already received the marketing permission for this drug in India for Visceral Leishmaniasis and is in process of conducting clinical trials for obtaining the permission in treatment of fungal infections. BSV has also conducted a Pre IND (Investigational New Drug) meeting with the US FDA for the clinical path and is in the process of filing the IND by Q1 2006.

The present anti fungal market is in excess of \$2 billion out of which the various Amphotericin formulation have a market share of in excess of \$300 million. BSVL expects that a safer Amphotericin formulation would be in a position to capture a substantial share of the global anti fungal market.